

### REMARKS

Claims 1, 3-4 and 8-20 were pending. Claims 5-7 were previously withdrawn. Claim 2 has been previously canceled. Claims 1, 3-4, 8-20 have been amended in this response. No new matter is believed to have been added by the amendments. This Amendment and Remarks document is submitted in response to said Office Action.

The Examiner has noted that rejections and/or objections not reiterated from the previous Office actions have been withdrawn.

### Rejection Under 35 U.S.C. § 103:

The Examiner has maintained the rejection of Claims 1, 8-11 and 14-18 under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 6,471,993 (herein referred to as '993), in view of U.S. Patent Publication No. 20060035350 (herein referred to as '350). The Examiner bears the burden of establishing a *prima facie* case of obviousness (Section 103). In determining obviousness, one must focus on Applicant's invention as a whole. *Symbol Technologies Inc. v. Opticon Inc.*, 19 U.S.P.Q.2d 1241, 1246 (Fed. Cir. 1991). Accepted rationales for obviousness include a combination of prior art elements according to known methods to yield predictable results; simple substitution of one known element for another to obtain predictable results; use of known technique to improve similar products in the same way; or applying a known technique to a known product ready for improvement to yield predictable results. *KSR v. Teleflex*, 550 U.S. 398, 127 S. Ct. 1727, 82 U.S.P.Q.2d 1385 (2007).

Specifically, the Examiner indicates that regarding the limitation that the ingredients are melt-mixed homogeneously, '993 teaches the need for the polymer, active ingredient, and porogen (solid fat), to be mixed homogeneously and asserts that the ordinary artisan would understand that melt mixing is an equivalent means of mixing the polymer, active ingredient and porogen together to ensure homogeneity and it would have been obvious to try to melt mix as an equivalent means of mixing the polymer, active ingredient, and porogen. The Examiner also asserts that the amount of a carrier would be greater than the amount of active ingredient, and the amount of porogen would be even greater.

Solely to expedite prosecution and without acquiescing in the rejection, Applicants have amended Claims 1, 8-11 and 14-18 to methods for preparing **nanoscale particles** which is not obvious in view of the combination of the teachings of '993 and '350 as neither teaches

preparation of nanoscale particles. Both '933 and '350 relate to a method for forming many voids in a polymer with no teaching of preparing nanoscale particles. In both references, a polymer is dissolved in a suitable solvent and lipid particles such as a porogen are uniformly dispersed in the polymer solution. The particles are then removed by dissolving them in a solvent which can do so. Neither '933 nor '350 alone or in combination teach or suggest the method of preparation of nanoscale particles as claimed and thus Claims 1, 8-11 and 14-18 are not obvious in view of the combination of '993 and '350 and respectfully request withdrawal of this rejection.

### **Rejections Under 35 U.S.C. § 112-Indefinite**

The Examiner has rejected Claims 3-4 and 8-20 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner asserts that the phrase "rapidly cooling" is a relative term and not defined by the claim and that the specification does not provide a standard for ascertaining the requisite degree, thus one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. To comport with § 112's definiteness requirement, the boundaries of the claim, as construed by the court, must be discernible to a skilled artisan based on the language of the claim, the specification, and the prosecution history, as well as her knowledge of the relevant field of art. See *Halliburton Energy Servs., Inc. v. M-I LLC*, 514 F.3d 1244, 1249-51 (Fed. Cir. 2008).

The purpose of rapidly cooling the melt-mixed mixture in the present invention of Claims 3 and 4 is to solidify the mixture in a short period of time. As disclosed in the specification of the present invention, in various preferred embodiments, rapidly cooling the melted mixture is for the purpose of solidification of the mixture and that it is preferred to rapidly decrease the temperature of the solution of the melted mixture to the temperature of 10°C or less (page 10, lns 10-11, 21 and 28-30 of the specification). In addition, the specification discloses that "[w]hen cooling is conducted slowly, crystal growth of the active ingredients may occur, and under such circumstances, the nanoparticles of the active ingredients are hardly achieved. . . ." (page 10, lns 30-32). In light of this, the exemplified rapid cooling procedure (i.e. pouring into a pre-cooled stainless steel plate) is only a preferred embodiment and the technical feature of the "rapid cooling" does not lie therein. Accordingly, any method (e.g., spraying at low temperature for

example as disclosed on page 12, second paragraph and Example 1 of the specification) capable of solidifying the mixture in a short period of time can be employed in the present invention of Claims 3 and 4 and their dependents. A skilled artisan would be well aware of various methods to achieve the solidification of the mixture via rapid cooling of the mixture as described in the specification and thus could select a method for rapidly cooling the melt-mixed mixture.

In addition, there are numerous issued US Patents that use the term “rapid cooling” in their claims (see for example U.S. Patent Nos, 6,362,214 (claim 2) and 6,410,130 (claims 3, 18, 19) without defining “rapid cooling” in the claims. Thus at the time of the invention, the phrase “rapidly cooling” was a term well known and understood by those of skill in the art.

In view of the above remarks, the phrase “rapidly cooling” is not indefinite as it discernible to a skilled artisan in view of the specification and knowledge of the relevant field of art. Applicants therefore respectfully request this rejection be withdrawn.

The Examiner has rejected Claims 1, 3, 4 and 8-20 under 35 U.S.C. § 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. Specifically, the Examiner asserts that the omitted steps in independent Claims 1 and 4 are: “Wherein step (2) is performed at a temperature below the melting point of the solid fat”. Solely to expedite prosecution and without acquiescing in the rejection, Applicants have amended Claims 1 and 4 to address this matter and therefore respectfully request withdrawal of this rejection.

#### Closing Remarks

If it would be helpful to obtain favorable consideration of this case, the Examiner is encouraged to call and discuss this case with the undersigned.

This constitutes a request for any needed extension of time or excess claim fees and an authorization to charge all fees therefore to deposit account No. 19-1970, if not otherwise specifically requested. The undersigned hereby authorizes the charge of any fees created by the filing of this document or any deficiency of fees submitted herewith to be charged to deposit account No. 19-1970.

Respectfully submitted,

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